RCPA
The Royal College of Pathologists of Australasia

Functional Requirements for Laboratory Information Systems to support

Structured Pathology Reporting of Cancer Protocols

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About this document

Most Anatomical Pathology departments in Australasia are operating with Laboratory Information Systems (LIS) whose functionality is based upon narrative reports using variations of word processing software with limited formatting capability. The vast majority of LIS do not provide functionality to support entering data in a structured format nor support storing this data atomically for reporting purposes or sending this data in atomic format to registries. Therefore, the purpose of this document is to describe the functional requirements for LIS to support structured pathology reporting.

This document is intended for laboratory system vendors, laboratory system information managers and those responsible for the acquisition of laboratory systems. The information in this document cannot be considered exhaustive but it does describe the key concepts and functionality required in an LIS to support structured reporting.

The document is comprised of two key sections – the first describes the structure, key concepts and features of structured reporting. The second section is a list of functional requirements. It is essential that Section 1 is read in conjunction with the functional requirements to ensure the meaning of the requirement is clear.

Examples are included throughout the document; in many cases these are a reference to a standard or guideline and protocol eg S3.05 Gastric; in other cases an excerpt from a protocol is included in an example box.

Document History

Version	Description	Date
Version 0.0	Initial draft	Dec 2010
Version 0.1	Review copy - internal	Jan 2011
Version 0.2	Reviewed by David McKillop, NEHTA	Feb 2011
	Reviewed by SPR Project Group	Feb 2011
Version 1.0	Final version for LIS vendors and Information System Managers meeting 15th March 2011	Mar 2011
Version 1.1	Revised version following 15th March 2011 meeting for internal review	Mar 2011
Version 1.2	Internal review and revision of V1.1	Apr 2011
Version 1.3	Revised version following 2nd LIS vendors and Information System Managers meeting 3rd May 2011 meeting	May 2011
Version 1.4	Internal review and revision of V1.3	May 2011
Version 1.5	Updated after the 3rd LIS vendors and Information System Managers meeting May 11th 2011	May 2011
Version 1.6	Version for review and endorsement by CanSAC	June-Sept 2011
Version 2	Version for endorsement by RCPA Council	Nov 2011

Definitions

Abbreviation	Full term
AJCC	American Joint Commission on Cancer
CAP	College of American Pathologists
CNS	Central Nervous System
CPAC	Canadian Partnership Against Cancer
LIS	Laboratory Information System
NEHTA	National e-Health Transition Authority
NPAAC	National Pathology Accreditation Advisory Council
RCPA	Royal College of Pathologists of Australasia
RCPath	Royal College of Pathologists UK
SPR	Structured Pathology Reporting

Introduction

In 2007, the Cancer Institute NSW convened a National Round Table meeting on structured pathology reporting drawing together the major players in pathology across Australasia. The report of the outcomes from the meeting documented a number of initiatives in structured reporting in progress around Australia. It was apparent from the data captured before and during the meeting that a number of cancer specific initiatives were underway, but clearly indicated that each was being developed in relative isolation creating a concern that each project may end up reporting to a different standard.
The value of Structured Pathology Reporting was clearly recognised at the meeting, and it was agreed that "cancer care in Australia would benefit from the development, publication and adoption of a series of national structured reporting standards for each cancer type".

In February 2008, the Cancer Institute NSW secured funding from the Dept of Health & Ageing (Quality Use of Pathology Programs) to work with the RCPA and Cancer Australia to develop an initial 6 reporting protocols (lung, melanoma, breast, colorectal, lymphoma and prostate) and a framework to guide development of the protocols, in partnership with national clinician and pathologist organisations. At the conclusion of the first phase of the project, six cancer protocols had been developed in addition to a comprehensive framework for the development of future cancer protocols.

A second round of funding from the Dept of Health and Ageing (Quality Use of Pathology Programs) was obtained in 2010 to build on the initial project foundation to promote and expand the use of structured reporting of cancer. This program of work included developing further protocols in conjunction with international bodies and undertaking a national program of education on the developed cancer protocols (breast, melanoma, lung, lymphoma, colorectal and prostate).

The program has also provided support and assistance to other bodies such as Standards Australia (IT 014-06-05) and NEHTA, undertaking work in the areas of HL7 messaging of structured reporting for pathology.

This second program of work is scheduled for completion in Mar 2011.
In addition to raising the standard of cancer reporting in Australia and thereby ensuring an improved outcome for cancer patients, the development of national structured pathology reporting standards is key to ensuring long term support of the national e-health initiatives as well as providing standardised data which will populate cancer registries providing a comprehensive wealth of information for research and policy makers.

Section 1: Key SPR Concepts and Features

1. Scope

As at March 2011, structured reporting protocols for 12 cancers have been developed. An additional 12 are in process or planning. It is anticipated therefore that sites will be using a mixture of formats for the reporting of cancers including traditional report formats; SPR protocol formats for specific cancers and locally developed structured formats. At this stage the project is concentrating on the development of protocols for cancer but in the future it is hoped this will extend to include non-cancer pathology protocols.

The introduction of structured reporting in Anatomical Pathology will depend critically upon successful electronic implementation at the pathologist workstation.

Collaboration

The Royal College of Pathologists UK (RCPath) and the College of American Pathologists (CAP) have been engaged in cancer dataset development for some time and both have extensive lists of datasets posted to their respective websites. The RCPA has been engaged in discussions with CAP, RCPath and the Canadian Partnership Against Cancer (CPAC) (Canada are adopting the CAP protocols) and progress is being made to develop closer collaboration. In 2010, the RCPA and CAP entered into a Memorandum of Understanding (MOU) as did CPAC and CAP. A meeting of all parties in Nov 2010 furthered this collaboration and a recent meeting in Feb 2011 has concluded in the signing of a four-way collaboration agreement. The group has agreed to work together to standardise many of the terms used and in particular to review and standardise the mandatory items in our most common cancer protocols. While great strides have been made in this collaboration and all parties are keen to further the discussion this is a long term goal and does not immediately impact our progress. There are a number of commonalities to work on together; however there are also a number of differences, some of which are documented here. There is still a lot to work out and it is expected the discussion will continue for quite a while.

2. Protocol structure

The SPR protocols are published to:

www.rcpa.edu.au/Publications/StructuredReporting/cancerprotocols.htm

The format of the protocols is based on the National Pathology Accreditation Advisory Council (NPAAC) style guide. This was used to facilitate the longer term inclusion of the use of structured pathology reporting in the laboratory accreditation process.

The basic structure of each protocol includes:

- preliminary material (scope, abbreviations, definitions, introduction and authority and development)
- the main body of the protocol
  - Clinical information and surgical handling
  - Specimen handling and macroscopic
  - Microscopic
  - Ancillary studies
  - Synthesis and overview
- checklist of all reporting standards and guidelines
- appendices (pathology request form, other reference data)
- references

Each of the main chapters (clinical, macroscopic, microscopic, ancillary and synthesis and overview) are comprised of 'items'. Items are either standards or guidelines and their commentary.

Standards
Standards are mandatory, prefixed with 'S' and numbered consecutively within each chapter (eg S1.02). Each standard is generally written to include the term 'must', eg 'The tumour stage must be recorded'.

Standards are reserved for core items essential for the clinical management, staging or prognosis of the cancer.

The summation of all standards represents the minimum dataset for the cancer.

Multi-component standards
Standards may contain more than 1 component eg from the Endometrial Cancer protocol, cervical involvement includes the evaluation of 3 separate components – mucosa, stroma and vascular:

S3.10 **CERVICAL INVOLVEMENT**

Involvement of cervical mucosa only:

Absent ___

Present & in-continuity ___

Present & separate ___

Involvement of cervical stroma:

Absent ___

Present & in-continuity ___

Present & separate ___

If present: ____ **mm (maximum) invasive depth (in histologic slide No:_____)**

out of ___ **mm normal cervical wall thickness**

Cervical vascular involvement:

Absent ___

Present ___

In the above example all the individual components are mandatory; however, in some cases there may be a need to evaluate components to see if all components are mandatory or only part. For example, from the Lymphoma Protocol, the specimen size is dependent on the type of specimen.

S2.04 **Specimen size:**

Biopsies (mm) ___

Fluid (mL) ___

Spleen (g) ___

In some cases this may be determined by precursor information such as the specimen type however in the above case, specimen type is a freetext field (given the variety of specimens that may be expected with a lymphoma). Therefore, the pathologist will need to make a decision as to which of the 3 categories to complete – they will NOT complete all categories.

Guidelines
Guidelines are recommendations; they are not mandatory, as are generally written with the inclusion of the term 'should' or 'may' eg 'The clinical diagnosis or differential diagnosis should be recorded'. They are prefixed with 'G' and numbered consecutively within each chapter (eg G1.10).

Guidelines cover items that are not essential for clinical management, staging or prognosis of a cancer, but are recommended. They include key observational and interpretative findings that are fundamental to the diagnosis and conclusion. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail. Guidelines are not used for research items.

Commentary
Commentary is text, diagrams or tables that clarify the standards and guidelines, providing examples and help with interpretation, where necessary.

Commentary is used to:

- define the way an item should be reported, to foster reproducibility
- explain why an item is included (e.g. how does the item assist with clinical management or prognosis of the specific cancer).
- cite published evidence in support of the standard or guideline
- state any exceptions to a standard or guideline.

Commentary is prefixed with 'CS' (for commentary on a standard) or 'CG' (for commentary on a guideline), numbered to be consistent with the relevant standard or guideline, and with sequential alphabetic lettering within each set of commentaries (eg CS1.01a, CG2.05b).

Eg from the prostate protocol:

G3.03	Lymphovascular invasion should be recorded.	
	CG3.03a	Lymphovascular invasion (LVI) is defined as the unequivocal presence of tumour cells within endothelial-lined spaces with no underlying muscular walls. Retraction and other artefacts should be excluded. LVI is an independent predictor of disease recurrence in multivariate analysis.[80-81]

Responses
Each item (standard or guideline) in the protocol will have a designated response. These responses may take the form of:

- Text/narrative (S5.02 Lung)

- Value list with single selection (eg radio button or pop-up menu)– which may be one or two values such as ‘present’ or ‘absent’ or consist of many values as in the case of a WHO histological tumour grade (S5.01 CNS)
- Value list with multiple selection (eg tick boxes)
- Value list plus text. In some cases one or more of the responses in a value list may require further detail such choosing an ‘other’ option (S1.06 CNS) or providing additional details if something is ‘present’ rather than absent (S3.13 Gastric)
- Numbers – such as weights and measures (S2.02 Prostate)
- Calculations. There are types of fields which can be calculated from one or more other fields.
    - These calculations may be numeric in nature eg S3.05 Melanoma where the mitotic rate is calculated as mm^2 which can be calculated from the number of high powered fields multiplied by the field diameter of the microscope.
    - They may also be calculated from the values entered previously such as the TNM stage - S5.01 Gastric tumour stage and stage grouping.
- Conditional fields which rely on the response to a previous question eg G3.03 Melanoma is conditional on a response of ‘present’ to S3.04 or G3.04 Soft Tissue which is only answered in respect of nerve sheath tumours.

Checklist

The checklist in Chapter 6 (‘checklist’) of the protocols includes the standards and guidelines in the simplest possible form. Only those standards and guidelines which must be considered when *reporting* are included; those standards and guidelines which pertain to specimen handling techniques etc are not included in the checklist.

The checklist may indicate repeated sections for different lymph node locations or multiple lesions, eg from the thyroid protocol:

S2.11	**Macroscopic description of lesion(s):**		
	Multiple lesions?		
		No	___
		Yes	___
	If yes, indicate number and complete the following items for each tumour as appropriate		___
Lesion 1			
	Location		_____
	Appearance		_____ _____
	Borders:	**encapsulated**	___
		infiltrative	___
	Size in greatest dimension		___ **mm**
	Distance from nearest excision margin		___ **mm**

The checklist is a representation only and in fact the actual number of repeated segments may need to be more or less.

Guides and forms posted to the RCPA website with the protocols are also representations of the contents of the checklist. Guides and forms are provided as implementation aids.

Numbering of standards and guidelines

As part of the copyright requirements of the protocol, numbering of standards and guidelines must be retained in any rendition of the checklist, but can be reduced in size, moved to the end of the checklist item or greyed out or other means to minimise the visual impact.

3. Synthesis

Chapter 5 of a protocol is titled 'Synthesis and overview'. It includes 2 key but separate concepts, the recording of synthesised information and the diagnostic summary. The diagnostic summary is discussed below.

In general, the noun synthesis refers to a combination of two or more entities that together form something new. Information that is synthesised from multiple modalities is described in Chapter 5.

For example. tumour stage is synthesised from multiple classes of information – clinical, macroscopic and microscopic. By definition, synthetic elements are inferential rather than observational. Tumour type and tumour grade may also be included in Chapter 5 where information other than microscopic such as clinical and ancillary studies is used to make a final determination.

Synthesis is not a one-off event. Information is synthesised each time new information is provided. For example, the initial synthesis of information included in the pathology report may not include pending ancillary findings or possibly the clinical information is poor; further investigations and additional specimens may also provide new information which results in a re-evaluation of previous conclusions (synthesised information). Staging is a good example of this. Staging for the initial report will be pathological only given the information at hand to the pathologist. However at the multidisciplinary meeting additional clinical and radiological information may change the staging.

At this stage the immediate requirement is to be able to include the items in the protocol for a single pathology reporting event. However the possibility of supplemental reports and the synthesis of new information needs to be taken into account in further report iterations.

4. Diagnostic summary

In each protocol the expert committee have stated what should be included in the diagnostic summary as a minimum eg from the prostate protocol

G5.01 The 'Diagnostic summary' section of the final formatted report should include:

a. specimen type (S1.03)

b. tumour type (S3.01)

c. Gleason score (S3.02)

d. tumour stage (S5.01)

e. whether or not the specimen margins are involved (S3.04)

This section captures the key 'highlights' of the report for quick and easy assimilation by the reader of the report. These items are all pre-existing in the protocol. The response information for the diagnostic summary should be assembled by the LIS, thereby avoiding the need for the pathologist to repeat the information.

Also included in Chapter 5 is the overarching comment. The overarching comment is used to document any noteworthy adverse gross and/or histological features and express any diagnostic subtlety or nuance that is essential to a complete understanding of the report as well as to document any further consultation required or results still pending.

Diagnostic Summary

Radical prostatectomy:

Adenocarcinoma, Gleason (ISUP 2005) 4+3 = 7, tertiary grade 5, AJCC Stage T3a, N0, M0; margin involvement (R1).

Comment: 1. Focal urothelial carcinoma *in situ* (CIS) is noted in the prostatic urethra. The urethral resection margin appears clear.
2. Equivocal margin involvement (due to crush artefact) by prostatic adenocarcinoma is noted at the apex focally.

5. Text / narrative

A common misconception is that structured reports do not include text/narrative. This is not true. Structured reporting uses text or narrative strategically. While the protocols includes text or narrative based responses to certain items, any item (standard or guideline), of any response type (numeric, value list), should provide for an additional comment to be added. It is extremely important that nuance and uncertainty is captured in context. Comments like this need to be inserted at the point in which they are required and the link between the response and comment needs to be established to avoid any possibility that the two are disassociated through the formatting or messaging of the report.

6. Synoptic / Structured

The words synoptic and structured are often used synonymously but there is a significant difference.

The use of the term synoptic reporting has been used with respect to Anatomical Pathology reporting for many years. The College of American Pathologists refer to the use of their checklists in reporting as 'synoptic' reporting. In essence, synoptic reporting refers to a synopsis of key points from an essentially narrative report usually contained in the conclusion or 'diagnosis' section of the report. The synoptic components are generally comprised of short responses often from a value lists such as present/absent, a list of tumour types, or list of sites for example.

A structured report is one in which the data is also primarily comprised of short responses from value lists but instead of summarizing the key elements, the structured format captures all of the elements across all sections of the report eg clinical, macro and microscopic, and uses narrative where ever necessary to expand or explain those elements. A structured report is wholistic in its approach – the protocols including all the elements (mandatory and optional) which may be reported for a particular cancer.

The advantage of a structured report is that in the longer term, all of the data is available for data mining, research and reporting not just the subset of elements included in the synopsis. A structured approach better supports the national e-health strategy but more importantly for pathologists, it enables decision support and more efficient, timely reporting.

7. Minimum to Maximum dataset

The design of the protocols as structured rather than synoptic has a significant impact on data entry, report formatting (rendering) and messaging. The use of a structured design is significant in that the checklist is expandable from a minimum dataset (standards only) to a maximal dataset (standards and guidelines) this means that a pathologist has the option to report or not, those guidelines they feel are necessary. This raises a number of points:

- It must be clear which items are standards and which are guidelines so that the pathologist may choose which of the guidelines is suitable to complete while ensuring all of the standards are completed.
- The report will need to cater for the variation in number of items completed – guidelines left blank during data entry must not be included in the report.
- As the protocol is wholistic in nature the same item may be recorded in more than one context. For example, the tumour size may be captured macroscopically as well as microscopically (S2.07 and S3.05 Gastric) . In data entry, reporting (rendering) and messaging the two concepts must be considered in context.

Note: This structured approach, encompassing a maximal dataset, is different to the US CAP model of synoptic reporting.

8. Multi-tumour

Many specimens will have tumours which are multi-focal, that is multiple tumours in the one specimen. In this situation there may be a requirement to record data for each tumour individually. This may occur macroscopically, microscopically or both. (S2.11 thyroid or G2.27, S2.03, G2.28, S2.04, S2.35, Kidney). While the checklist provides for a specific number this is a representation only and in fact a LIS will need to cater for 1-n tumours in a single specimen. In *most* cases these tumours will be of the same type and tumours which are of different types will need to be reported separately as they may have different staging and prognosis.

9. Release of a new edition

The implementation of SPR protocols will need to be edition based. Each published structured pathology reporting protocol is described by a bi-part version number eg V1.1. The first number indicates the edition and the second indicates a specific update to that version.

A new *edition* is created based on the following:

- Changes to any standard or guideline wording or numbering including deletions, new additions etc.*
- Changes to the meaning of any commentary eg new method of calculation.
- Changes to any core, dependent documents such as the AJCC Cancer Staging manual

An *update* to an edition may be released for the following reasons:

- Formatting updates
- Minor modifications including:
  - Minor corrections eg spelling, punctuation,
  - Reference updates
  - Rewording of commentary which does not change the meaning but is for the purposes of clarification only.

*All standards and guidelines are numbered within the protocol according to the chapter in which they appear and the order in which they are documented eg S1.03 is the 3rd standard in chapter 1. Commentary is added by the use of a, b, c etc.

However, this numbering of standards and guidelines should be viewed in the context of the edition of the protocol in which it is documented.

This edition specific numbering is important as numbering of standards and guidelines may change overtime as new editions are released. For example, the release of 7th edition AJCC cancer staging manual in Oct 2009 brought with it a change for the documentation of Clark level in the Melanoma protocol from a standard to a guideline – this not only changed the numbering for this specific item but also for all subsequent items in that chapter.

Version updates, due to their minor nature, do not necessitate an update in any LIS.

Release schedule

A new or updated edition of each protocol will be undertaken as follows:

- An initial review and update 12months from the first publication date.
- General review and release 3 yearly from the first publication date.
- New edition update on release of the 8th and subsequent editions of the AJCC cancer staging manual.

Updates to editions may be released earlier than this review period if deemed applicable by the chair, lead author and authoring committee.

10. Data entry

The change from narrative to structured reporting will require a much improved LIS interface if this is to be achieved without an increased burden on the workforce and the data entry flow should be streamlined to ensure that the speed of reporting is not compromised.

The field order needs to follow pathologist workflow and preset value lists should be available contextually depending upon information already entered. To achieve maximum benefit, and to avoid entering information twice, macroscopic information (recorded at the time of specimen dissection) will need to be structured similarly to microscopic and ancillary information. Speech activated responses may be especially important for macroscopic information.

A number of requirements have been included to support this.

11. Reporting

Traditionally the way that a pathology report has been entered is the way in which it has been reported to the clinician caring for the patient. This was largely as a result of the word processing style of data entry.

There is however, a significant difference in functionality to support streamlined and speedy data entry and functionality to support the clear and accurate assimilation of key information by the clinician reading the report. The functionality of the LIS needs to support these two separate but important functions.

The pathology report – whether viewed on screen or printed needs to support a style where the key information such as the Diagnostic Summary and overarching comment is displayed clearly and preferably it must appear as the first part of the report. This information contains the vital information needed by the clinician when treating the patient. The remaining components of the report are supporting information or additional detail.

As a structured protocol covers a minimum dataset through to a maximal dataset – the final formatted report needs to adjust to this variation. In addition, the items must be reported in the context or section in which they are recorded such as the macro or micro section. For example, a tumour diameter in both the macro and micro sections of a report may be different values and as such, it is vital that the context (macro or micro) in which the information was recorded is included in any report.

Note that the inclusion of structure/context in relation to standards and guidelines is another key difference between the US and Australian models. The synoptic components of the CAP protocols are non contextual – that is, they are not reported as having been recorded in the macro or micro for example.

A number of functional requirements are included on reporting in Section 2.

12. HL7 messaging

Archetypes
The first 6 protocols - published in Feb 2010 have been developed into archetypes by Ocean Informatics in OpenEHR. The fine tuning of these archetypes and development of additional archetypes for new protocols will evolve over the next several months as we engage in a pilot implementation in conjunction with NEHTA.

Implementation Guide
NEHTA has commissioned Medical Objects to develop an implementation guide called "Archetype data in V2" which will provide guidance around incorporating structured pathology reports into HL7 V2 messages.

Of note, Standards Australia in conjunction with various other IT organisations, is undertaking a review and update to the Australia Standard 4700.2-2007 "Implementation of Health Level Seven (HL7) Version 2.4 - Pathology and medical imaging (diagnostics)" and the Handbook HB 262 "Guidelines for pathology messaging between pathology providers and health service providers".

IHE
The International Integrating Healthcare Enterprise (IHE) (an initiative designed to stimulate the integration of the information systems and which defines technical frameworks for the implementation of established messaging standards to achieve specific clinical goals) released its Technical Framework for Anatomic Pathology Structured Reports (APSR) in August 2010, prompted by Spanish and French efforts in structured reporting. On review of the framework a number of points of concern where raised largely based on the fact that the framework used a traditional narrative based pathology report with synoptic items in the conclusion as its basis. This is at odds with the approach taken by Australia with its structured rather than synoptic style. It is anticipated that further discussion will occur on this.

13. Compliance

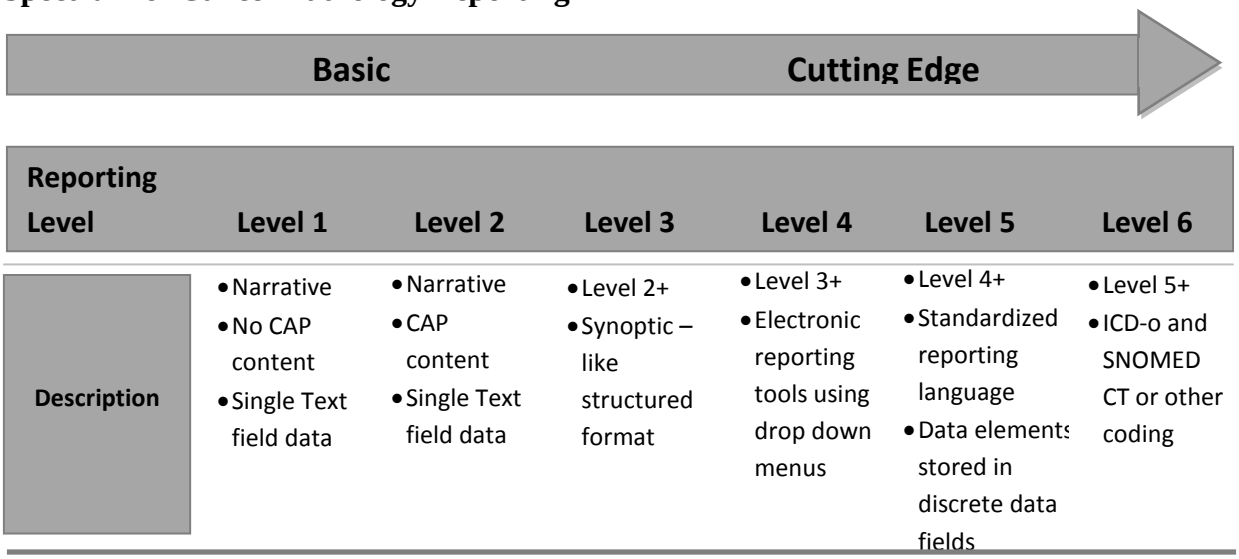
NPAAC
The format of the protocols is based on the National Pathology Accreditation Advisory Council (NPAAC) style guide. This was used to facilitate the longer term inclusion of the use of structured pathology reporting in the laboratory accreditation process. Currently the SPR protocols are included as Tier 6 documents in the NPAAC document hierarchy. Tier 6 documents are 'documents of interest' or reference documents to other standards. It is anticipated that the protocols will be advanced to Tier 3 or 4 in the next 2-3 years at which time they will be used in the accreditation process. This 2-3

year period is a time of bedding down and refining of the protocols before they are included in the accreditation process.

Progress to compliance

In a 2009 paper[1] on Synoptic Reporting, Srigley et al included the different levels – 1-6 that chart the progress from a traditional model of reporting to a fully structured and encoded report. The following diagram from his article encapsulates these 6 stages. This model is applicable for Australia by replacing the "CAP content" with the "RCPA Structured Reporting content".

Spectrum of Cancer Pathology Reporting[1]



In the first instance we expect that sites implementing Structured Reporting will achieve Level 4 with the data being captured in conformance with the protocols using appropriate date entry mechanisms. In the longer term we expect to reach level 6, being fully atomic and encoded.

14. Copyright

The SPR protocols are based on a review of evidence in the latest peer-reviewed literature to ensure that pathology reports contain the most recent and evidence-validated information. To this end the protocols contain key reference information such as the World Health Organisation classification of tumours, the AJCC cancer staging information amongst others.

These reference lists – often comprising the value lists to responses must be included in the LIS. In order to achieve this copyright must be sought from the source.

[1] SRIGLEY JR, MCGOWAN T, MACLEAN A et al "Standardized Synoptic Cancer Pathology Reporting: A Population-Based Approach". Journal of Surgical Oncology 2009;99:517–524

15. Additional reading

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- Edge S, Byrd D, Compton C, Fritz A, Greene F and Trotti A (2009). *AJCC Cancer Staging Manual 7th edition*. Springer-Verlag, New York.

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Section 2: Functional Requirements

Definitions

Mandatory A rating of mandatory is assigned to those functional requirements deemed **essential** to adequately support structured pathology reporting.
The summation of all mandatory items represents the minimum requirements to be met by a Laboratory Information System (LIS) to be considered capable of supporting structured pathology reporting.
In this document, mandatory items are prefixed with 'M' and numbered consecutively.

Recommended Recommended items are not mandatory however they constitute those functional requirements which elevate the LIS functionality beyond that which is essential to meet the minimum requirements for structured reporting, and which improve useability for the pathologist.
In this document, guidelines are prefixed with 'R' and numbered consecutively.

Commentary Commentary is text and examples that clarify the mandatory and recommended items. Commentary is prefixed with 'CM' (for commentary on a mandatory item) or 'CR' (for commentary on a recommended item), and are numbered to be consistent with the relevant item, and with sequential alphabetic lettering within each set of commentaries (eg CM1.01a, CR2.05b).

1. Data Entry - Layout

M1.1 Standards (mandatory items) must be clearly indicated to the pathologist as distinct from guidelines (optional items).

CM1.1a It must be clear to the pathologist while reporting (data entry) which standards are not yet completed in order to comply with the minimum dataset requirements.

M1.2 Data entry layout suitable to the response type and known value lists must be provided.

CM1.2a This includes text, check boxes, radio buttons, pop-up menu, drop down list eg value list with multi–select or single select capability; calculations, etc.

CM1.2b Where a specific format of entry is required such as ___mm or ___g or a multi-part measurement such as __x__x__mm the LIS should provide this in the response field to guide the response and where applicable include any units as part of the response.

M1.3 Conditional fields must only appear as and when indicated by the response to the precursor response.

CM1.3a This logic must apply to subsequent items such as another guideline or standard as well as to 'other' fields within the same standard or guideline.

M1.4 A preview of the draft report must be easily available at all times, with quick and easy access back to a standard or guideline from within the preview.

CM1.4a The reporting pathologist needs to be able to view the draft report at any point during the reporting process. This access must be quick and easily accessible and should not require the pathologist to exit from the reporting screen.

CM1.4b The value of previewing a report is to identify issues in the report and to quickly correct them. A pathologist must be able to click on any part of the previewed report to quickly access that standard or guideline in a data entry mode for easy editing.

R1.1 The item (standard or guideline) that is being addressed should be easily identifiable at a quick glance.

CR1.1a The pathologist should always be able to see exactly where they are in the reporting process. It is important when working between the microscope and the computer screen that the pathologist is not constantly evaluating 'where they are up to' on the screen each time they look back.

R1.2 Once a field is complete the cursor should move automatically to the next required response.

CR1.2a This does not apply to multi select fields where the pathologists may select several responses.
CR1.2b Alternatives to a mouse driven 'next key' must be available eg TAB key – preferably this is user selectable.

R1.3 The sequential order of the standards and guidelines as it appears in the published protocols should be maintained

CR1.3a Maintaining the sequential order of the standards and guidelines as it appears in the published protocols ensures consistency between laboratory information systems. This ensures an easy transition for pathologists working at multiple laboratories.
CR1.3b The order of standards and guidelines is integral to maintaining the flow of conditional fields.
CR1.3c Presenting the order of the fields as it appears in the published protocols should not prohibit the pathologist from entering data in an order applicable to the case under review.

R1.4 The data entry screen should be configured for optimal reading and navigation.

CR1.4a Adequate white space and a font size for optimal reading are essential.
CR1.4b The value of pop-up windows versus scrolling fields should be considered in the context of the data to be displayed eg short lists, long hierarchical lists, text field etc.
CR1.4c The values corresponding to the item must also be clear and of a reasonable size.

2. Data Entry – Content

M2.1 The pathologist must be notified and asked to complete those standards (mandatory fields) that have not been completed when attempting to verify the report (signout).

CM2.1a A warning should be triggered to the pathologist if they try to verify/finalise a report without all the standards completed. This should prompt the pathologist with a list of those mandatory fields which are not complete and provide quick access to those fields.

CM2.1b In the case of multi-component standards a determination needs to be made as to whether the completion of part of the components satisfies the intent of the standard.

M2.2 The list of mandatory fields must be dynamically updated whenever fields are completed, altered or deleted.

CM2.2a Where a standard or guideline is specific to a particular location or type of tumour eg S2.11 Colorectal "Intactness of mesorectum" which is applicable to rectal resections only, then this item should not require a response/nor should it appear unless the values triggering it change. If this is a standard then this should not trigger the warning to complete the field (M1.2) as it is not applicable.

M2.3 Text field size must not be limited.

CM2.3a Variable lengths of response must be accommodated by scroll bars, or other dynamically updated field sizing.

M2.4 Responses must be validated where applicable.

CM2.4a For each type of response, validation of the response according to the specific type should be included eg numeric, alpha-numeric etc.

CM2.4b For numeric values – logical constraints should be added – eg specimen size is 10x12x2mm then the tumour size cannot exceed these parameters.

CM2.4c Where a measurement is expected then a numeric value should be expected and in this case the laboratory should be able to determine the upper and lower limits expected from the response to avoid gross errors.

M2.5 There must be dynamic updates of any calculation fields.

CM2.5a Modifications to any calculation precursors should automatically update the calculation.

M2.6 If a field which has dependent conditional response(s) is changed, then the conditional response(s) must be adjusted dynamically (removed, changed) as necessary.

M2.7 A pathologist must be able to add in a comment against any individual standard or guideline.

CM2.7a Structured pathology reports use text strategically and it is vitally important to be able to include a comment which clarifies a response.

M2.8 A pathologist must be able to add a comment/caption to a diagram or image as required.

CM2.8a Arrows and other direct annotations to any image or diagram must be incorporated into the image or spatially "locked" in some other way to avoid dissociation of the two.

M2.9 All patient demographic information, and any provider and organisational identifiers must adhere to established standards.

CM2.9a Existing Australian Standards, National data dictionary (AIHW), and NPAAC standards exist which describe how information such as patients gender, date of birth, date of request, provider numbers (IHI) etc are defined.

CM2.9b Demographic information is the key to data linkage and to cancer epidemiology in the longer term and therefore it is important that they comply with the national data dictionary.

M2.10 More than one RCPA SPR template should be able to be used during reporting if required for any one specimen or episode.

CM2.10a Some cases may need more than one template to complete reporting of the case eg multiple synchronous tumours.

R2.1 Automatic calculation of staging should be included.

CR2.1a Staging is the categorisation of previous information. In many cases this information has been clearly entered in previous fields – eg diameter of tumour. Therefore automatic calculation of staging should be possible.

R2.2 The Diagnostic Summary should be automatically compiled from entered data.

CR2.2a The diagnostic summary is comprised of a group of fields already covered by existing responses and as such can be automatically compiled according to the criteria detailed in the protocols. See below:

From the Thyroid Cancer protocol...

From the protocol:

G5.01 The "Diagnostic summary" section of the final formatted report should include:

a. Operation type (S1.05)

b. Tumour site and laterality (S1.07 and S1.08)

c. Tumour type (S3.01)

d. Tumour stage (S5.01)

e. Completeness of excision (S3.05).

From the example report:

Total thyroidectomy, Right upper lobe, Papillary carcinoma, Stage pT1a, pNX (AJCC 7th edition, 2010)**, Resection margins negative**

R2.3 Where an item appears in more than one context eg macroscopic as well as microscopic, then the pathologist should be presented with this information for review and comparison at the point of data entry of the subsequent item.

CR2.3a For example, where information is entered from the request during the accessioning process eg the specimen type etc then this information should display (where applicable) at the point at which the same information is required in the clinical or macroscopic section of the structured report.

CR2.3b In another example, where the information is entered both macroscopically and microscopically (see example box below) then the macroscopic information should be displayed to the pathologist at the point where the the same information is required in the microscopic.

From the Central Nervous System Tumours protocol...

MACROSCOPIC FINDINGS		
G2.12	Macroscopic distance between tumour and nearest dural resection margin (where dura is included)	___ **mm**

MICROSCOPIC FINDINGS		
G3.02	Distance between tumour and nearest dural resection margin (where dura is included)	___ **mm**

R2.4 A pathologist should be able to add in a diagram or image against an individual standard or guideline.

R2.5 LIS systems should appropriately escape the HL7 V2 encoding characters such as &,^, ~,\, which may cause problems when transmitting and receiving messages containing these characters.

CR2.5a Alternatively the pathologists should be warned when using any problematic characters such as & ^ ~ at the time of data entry.

CR2.5b Note Standards Australia's committee IT014-06-05, will be producing an Australian Technical Report (ATR) - "Guide to HL7 V2 message parsing and management of character escaping with reference to backward compatibility" in 2011 which may be of assistance.

R2.6 Standard comments should be able to be stored for easy retrieval during reporting.

CR2.6a Often a pathologist will use a comment on multiple occasions – to avoid typing the same comment each time the pathologist should be able to type and store a comment for later use at any time.

CR2.6b Comments should be able to be stored for individual use or for use by multiple pathologists.

3. Data Entry - Help

M3.1 Contextual help must be provided at the point of data entry of that item.

CM3.1a Contextual help, in the form of access to the relevant section of the protocol, must be provided at the point of data entry of that item. This may include diagrams and tables and should be accessed with a single click or hyperlink.

R3.1 Spell check on text entry fields should be made available at the discretion of the pathologist.

CR3.1a Spell check needs to include medical terminology to be effective and to avoid excessive warning of incorrect spelling.

CR3.1b Spell check should allow local user editions and/or additions.

4. Data Entry – Medium

M4.1 The macroscopic findings must be able to be entered in structured manner.

CM4.1a The structured pathology reporting template includes structured data in each of the sections of the report eg clinical, macroscopic, microscopic etc. The macroscopic which has traditionally been dictated as a long narrative requires functionality to support similar ease of entry but in a structured format.

R4.1 Data entry for both narrative and defined values should be speech recognition enabled.

CR4.1a Speech recognition needs to be optimized to cater for a structured method of entry - for example pathologists should be able to say 'next field' and have the system move to the next field automatically.

R4.2 Data entry for defined value lists should be touch screen enabled.

5. Data Entry – Structure

M5.1 The application needs to cater for multiplicity within the report eg multiple tumours in one specimen.

CM5.1a To allow for multiple tumours within one specimen, the system must allow for n-number of repeated groups of fields if indicated by the protocol. These fields may be a group of questions under a single standard or guideline or may be multiple standards and guidelines.

M5.2 Terminology coding must be able to be assigned to standards, guidelines and any value lists.

CM5.2a For example, SNOMED CT, LOINC or Australia Medical Terminologies (AMT) or other recognised codes must be able to be assigned.

R5.1 User preferences should be provided.

CR5.1a User preferences, which tailor the data entry layout and content to assist the pathologist is highly desirable. These include but should not be limited to:

- Where a required calculation is dependent upon further static information (such as the field diameter of a microscope - used to determine the mitotic rate in mm^2 based on number of high powered fields) then this should be made available as a user preference setting to be entered for any given environment.
- The pathologist should be able to specify the 'next'/'move on' key.
- The pathologist should be able to specify whether text fields are automatically spell checked.

6. Data Entry - Value lists

M6.1 Value lists must be accessible to the pathologist, in full at the point of data entry.

CM6.1a Any coded or numeric type value list (such as AJCC cancer staging ie pTX, pT2 etc) should be accompanied by the descriptor so that the pathologist has sufficient information to make an informed choice.

M6.2 All responses must be modifiable to a null response.

CM6.2a For example, if a value is selected from a list then it must be possible to alter this to a "Null" or "empty" response with a single click or selection.

R6.1 Value list layouts must be optimized for clarity and speed of entry.

CR6.1a The number of choices in pop-up menus, drop down lists and check boxes should be optimised where possible eg to 10 choices or less. Some large value lists such as WHO tumour types (>70 in some tissues) may be best selected hierarchically using the subheadings provided by WHO. Other large list such as antibodies assessed as positive, negative or other may be best offered as a full screen multi-select check box set.

R6.2 The ability to sort value lists by frequency or preference should be provided.

CR6.2a This includes dynamically sorted or 'on the fly' sorted value lists based upon frequency of use ie most commonly answered responses.

CR6.2b Value lists may be manually sorted based on a pathologist's preference ("favourites").

7. Data Messaging

M7.1 Interfaces to any external systems must be compliant with the standard AS4700.2 and HB262.

8. Data Reporting

M8.1 The integrity of headings, values, comments and images must be maintained.

CM8.1a Structured reporting items (standards and guidelines) must be reported together with, and in the context of any parent headings and subheadings. Comments, diagrams and images must be visually linked to the relevant data element and its heading.

CM8.1b Additional headings to facilitate organisation of the information may be added where appropriate.

M8.2 The system should be capable of integrating results from other laboratories from within the same Enterprise LIS.

CM8.2a This includes for example results of molecular assays, cytogenetics, flow cytometry etc. reported separately but pertaining to the same specimen. These will usually appear within the Ancillary Tests section of a report.

M8.3 Report formats must cater for the variability in number of items reported.

CM8.3a Where a response is not given, the field and title must not appear and subsequent fields must slide upwards to remove unused space and maintain layout integrity.

M8.4 Hierarchies within data elements must be visually maintained.

CM8.4a Data hierarchies must be capable of emphasis by the availability of indents, font sizes and font styles for headings for example:

From the Renal Parenchymal Malignancy protocol...

MICROSCOPIC

Tumour

Tumour type:	Clear cell renal cell carcinoma
Tumour grade:	Grade 3
Sarcomatoid differentiation:	Absent
Rhabdoid differentiation:	Absent
Necrosis:	Absent

Extent

Tumour spread beyond kidney:	Absent
Tumour in renal sinus fat:	Present
Tumour in perinephric fat	Absent
Tumour in pelvi-calyceal system:	Absent
Tumour in adrenal gland:	Absent
Tumour in other organs:	Absent

Lymph nodes

Regional lymph node involvement:	Present
Site:	Renal hilum
No. of nodes present:	2

M8.5 Columnar style reports must be achievable (by indent or other means).

CM8.5a Columnar reports must maintain alignment and consistency across all media. This includes the pathologist data entry view /print preview (WYSIWYG), all printed or faxed versions, and all on screen versions including electronic downloads to the end user.

R8.1 **The edition number for any given protocol must be displayed or accessible in the report.**

R8.2 **The sequence of the items in the report must be maintained in an order deemed appropriate by the pathologist.**

R8.3 **The diagnostic summary and overarching comment should be prominently displayed on the report (on-screen or printed).**

CR8.3a This should be at the very beginning (preferred) or end of a report and visually separated from the rest of the report - or (supporting information) by visual cues such as font size or style, lack of indenting and use of surrounding white space.

R8.4 **Where appropriate, data tables should be available for optimal display and end-user assimilation.**

CR8.4a Any table formatted data must retain its consistency across different media.

R8.5 **Columnar or tabular reports should be printable on alternate horizontal white/light grey bands.**

CR8.5a In line with current publishing practice, columnar or tabular reports should be printable on alternate horizontal white/light grey bands to avoid parallax or line dropping in horizontal eye scanning.

9. Data Storage

M9.1 **Data must be stored atomically in the database for easy retrieval and messaging.**

10. Data Search/Query

M10.1 Functionality must be provided to enable extensive multi-parameter and conditional querying on stored data.

CM10.1a Data query/search functionality must allow the pathologist to enter multiple parameters equivalent to any standard, guideline or atomic response.

CM10.1b Queries should cater for multiple conditionality values such as greater than, less than, equal to, single or multiple parameters in combination.

M10.2 Queried data must be reported in context.

CM10.2a Structured reporting items and their responses must be reported together with, and in the context of any parent headings and subheadings eg if a query requests all gastric cancer with tumour site - fundus and antrum then this must either at the point of querying or in the returned query identify that both macroscopic and microscopic gastric tumour sites involving fundus and antrum are possible.

CM10.2b Additional comments, diagrams and images linked to the relevant data elements must be retrievable.

11. Dataset (Checklists)

M11.1 Where no RCPA equivalent cancer dataset exists, new datasets must be able to be created locally.

M11.2 New versions (editions) of a cancer specific protocol checklist must be able to be implemented quickly and simply.

CM11.2a Preferably this should be able to be achieved by copying a previous version and modifying when a new edition of the protocol is released.

M11.3 The integrity of previous versions (editions) of the checklists must be maintained.

CM11.3a When a new version of the checklist is included (based on a new edition of the protocol) the system must be able to maintain the integrity of previous versions in particular where cases have been started but not completed using a specific version.

R11.1 RCPA SPR templates should be modifiable on an individual or institutional level.

CR11.1a Additional mandatory or optional items may be added.
CR11.1b Guidelines may be deleted if not required.
CR11.1c As part of the copyright requirements of the protocol numbering of standards and guidelines must be retained in the checklist, but can be reduced in size, moved to the end of the checklist item or greyed out or other means to minimise the visual impact. Additional items for local use may be added but must not be numbered as a standard or guideline, in order to avoid confusion with the RCPA checklist items.

12. Other

R12.1 A simple means of communicating back to the RCPA should be provided.

CR12.1a Feedback on the protocols is vital to their further refinement. A simple means of communicating back to the RCPA should be provided such as link to email with the RCPA email address included in the 'to' field.